IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. ELLSWORTH ASSOC., LLP, Plaintiff,	:	**CIVIL ACTION**
v.	:	**NO. 19-2553**
CVS HEALTH CORPORATION, et al. Defendants.	:	

MEMORANDUM

Younge, J. **March 10, 2023**

Plaintiff Ellsworth Associates, LLP ("Relator") brings this *qui tam* action on behalf of the United States against Defendants CVS Health Corporation, SilverScript Insurance Company, LLC, CVS Caremark Corporation, and CVS Pharmacy, Inc., to recover damages under the False Claims Act ("FCA"), 31 U.S.C §§ 3729, *et. seq.* The Relator alleges Defendants engaged in an anti-competitive scheme to block Medicare Part D recipients from accessing less expensive drugs. The Relator further alleges that Defendants colluded to reap larger profits from brand-name drugs than would otherwise be realized from cheaper generic drugs, at the expense of the Government and federal program beneficiaries. According to Plaintiff, Defendants' scheme resulted in the submission of false claims for payment to the Government and wrongful retention of Government funds in violation of federal law, various state laws, and Defendants' agreement with the Federal Trade Commission ("FTC"). Now before this Court is Defendants' Motion to Dismiss Relator's Second Amended Complaint ("SAC") pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). (ECF Nos. 18 & 35.) For the reasons that follow, this Court denies Defendants' Motion as to Relator's FCA claims under 31 U.S.C. §§ 3729(a)(1)(A), (B), and (C) in Counts I, II, and III, but grants the Motion to Dismiss as to Relator's claim under § 3729(a)(1)(G) in Count IV.

I. BACKGROUND

In order to understand the Relator's claims herein, one must first understand how Medicare Part D operates. Therefore, the Court will discuss Relator's specific allegations in the context of the relevant legal and drug benefit landscape.

Medicare Part D is an outpatient prescription drug benefit for people with Medicare that is provided through private insurance plans, known as Part D Plans ("PDPs" or "Sponsors") that contract with the Government. (ECF No. 18 at 8-9, 25.); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017) (Medicare Part D's prescription drug benefit program "operates as a public-private partnership between [CMS] and…private insurance companies called 'Sponsors' that administer prescription drug plans.").

The prices of prescription drugs are determined through negotiations between the Sponsor's (or their pharmacy benefit managers "PBMs") and drug manufacturers, which, in theory, will reduce the costs of prescription drugs through market competition. (ECF No. 18 at 26; ECF 35-1 at 17.). As part of these negotiations, drug manufacturers may offer rebates, that are discounts off the drug list price, in exchange for Sponsors including certain preferred drugs on lists known as "formularies." (ECF No. 35-1 at 13.) The "formularies" determine which drugs are and are not covered by a Medicare Part D Plan and are often negotiated by PBMs. (ECF No. 38 at 15; ECF No. 35-1 at 11-12, 17.) Though these rebates can be important tools to lowering drug prices, they can also be used to create competitive restrictions that increase costs, as drug manufacturers may squelch out competition from cheaper drugs by conditioning the rebates on giving their product preferred status. (ECF No. 35-1 at 9.)

At its core, this is what Relater alleges occurred in this case along with other anti-competitive behavior.[1] Specifically, Relator alleges that Defendants, large vertically integrated or affiliated companies, colluded with drug manufacturers to financially benefit from an anti-competitive arrangement that blocked lower-priced drugs from gaining market share. (ECF No. 18 at 9.) Relator alleges this scheme was brought to light by Alexandra Miller, a partner of Relator, Ellsworth Associates, LLP, who previously worked for CVS for nineteen (19) years. (ECF No. 18 at 10, 18.) The Relator details fifteen (15) different drugs made by eleven (11) different drug manufacturers where less expensive drugs were prevented from competing in the SilverScript Medicare Part D marketplace due to anti-competitive agreements including for the following: Copaxone (Teva), Exelon (Novartis), Voltaren Gel (Endo), Invega (Janssen), Asacol HD (Allergan), Xopenex HFA (Sunovion), Renvela Packets (Sanofi), Renvela Tablets (Sanofi), Istalol (Bausch & Lomb), Harvoni (Gilead), Epclusa (Gilead), Ventolin HFA (GSK), Canasa Rectal Suppository (Allergan), Advair Diskus (GSK), Suboxone Sublingual Film (Indivior). (ECF No. 18 at 111; EC No. 38 at 23.) Relator alleges that the drug manufacturers paid rebates to ensure placement on Defendant SilverScript's formulary, and to prevent competition from less expensive generic drug equivalents, in a scheme that caused "significant increased costs to both Medicare and SilverScript beneficiaries alike." (ECF No. 18 at 8-9, 111.)

According to Relator, the decision to place these drugs on SilverScript's formulary was not the product of arms-length negotiations, but rather improper collusion between the drug manufacturers and entities all affiliated with Defendant CVS Health Corporation ("CVS Health") – the "largest provider of prescription and related healthcare in the United States." (ECF No. 18

[1] Relator also refers to a practice known as "evergreening" in which the lifetime of a drug patent is extended to retain revenues, "product hopping" where a drug manufacturer ceases production of an older drug to encourage a new formulation, and various "authorized generic schemes." (ECF No. 38 at 29; ECF No. 18 at 130.)

at 18.) With "all of its wholly-owned subsidiaries" serving in each separate role of the complex delivery of Part D benefits to SilverScript plan enrollees – from PBM, PDP to even pharmacy – Relator alleges that Defendants achieved an "enterprise-wide" benefit that "padded its bottom line." (ECF No. 38 at 29.) In particular, Relator alleges that Defendant SilverScript is a "corporate affiliate of CVS" which is the "largest PDP in the United States" while Defendant CVS Caremark Corporation, a "CVS subsidiary" is the PBM[2] for SilverScript, who administers the plan's formulary and pharmacy benefits. (ECF No. 18 at 18-20.) Defendant CVS Pharmacy, Inc., in turn, has nearly 9,900 retail pharmacies, many of which dispense the drugs for SilverScript plan enrollees, and is "owned and controlled" by CVS Health. (ECF No. 18 at 21.) The Defendant entities were supposed to be "firewalled"—meaning they should have had barriers preventing them from sharing sensitive information between each other that could result in unfair competition in the marketplace. Defendants were required to maintain these "stringent firewall protections between [its] CVS Pharmacy retail business and [its] CVS Caremark PBM business to prevent any anti-competitive activity" pursuant to a 2007 agreement with the FTC following the merger of CVS Health and Caremark. (ECF No. 18 at 84-86.) The "firewalls" were also required by a compliance program Defendants initiated following a Corporate Integrity Agreement CVS Health entered into with the Government in 2014 and 2016 for alleged healthcare fraud. (ECF No. 18 at 37-38.) By colluding together to financially benefit from the rebate agreements, Relator states that Defendants violated the required firewall between CVS-related entities that these agreements were designed to protect against. (ECF No. 18 at 10, 73, 85.)

To further Defendants' lucrative scheme, Relator claims that Defendants engaged in a variety of collusive and improper conduct. As to four brand-name drugs – Harvoni, Epculsa,

[2] Defendants state that CVS Caremark Corporation is not the proper PBM, but rather that CVS Caremark Part D Services, L.L.C. is the proper PBM. (ECF No. 35-1 at 17.) This is a matter better resolved after discovery.

Advair Diskus and Ventolin HFA – CVS Pharmacies stopped stocking the generic versions of these drugs due to the rebate agreements with drug manufacturers GSK and Gilead, eliminating any possibility that consumers could obtain cheaper generic equivalents at these pharmacies. (ECF No. 38 at 30; ECF No. 18 at 12.) Relator states that Defendants would also issue blanket denials of generic "formulary exceptions" including for several very expensive and life-saving drugs. (ECF No. 18 at 12.) A "formulary exception" is a type of request Medicare Part D plan enrollees can make to seek coverage for a drug not on Sponsor's formulary which beneficiaries have the right to request. (ECF No. 38 at 16.) Preventing formulary exceptions kept beneficiaries from getting less-expensive generic equivalents. Relator provides examples where this occurred, including several same-day denials of formulary exception requests to switch to generic drugs; Defendants' cited therapeutic and risk equivalence between the brand-name and generic versions as the reason for the denials, without consideration of whether a denial would prevent beneficiaries from accessing critical or life-saving prescription drugs. (ECF No. 18 at 193.) In one instance among many cited in the SAC, the brand-name prescription cost Medicare $20,872.59 when the generic version would have cost $6,871.15, and was refilled three more times, costing Medicare an additional $62,794.36. (ECF No. 18 at 193.) In another case, a formulary denial may have prevented a thirty-eight (38) year old beneficiary from completing his Hepatitis C treatment for a disease that can lead to death, despite him seeking a generic formulary exception stating he "cannot afford" the brand-name drug. (ECF No. 18 at 202.)

Relator claims Defendants also intentionally misled SilverScript plan enrollees with deceptive statements indicating that generic alternatives would be more expensive or were not available. (ECF No. 38 at 48.) Defendants accomplished this by various misleading marketing material and requiring customer care representatives to make false and misleading statements to

beneficiaries. (ECF No. 18 at 11.) Relator provides several SilverScript predetermined call flows and training instructions that appear to be designed to mislead, along with specific instances where beneficiaries were misled by customer care representatives. (ECF No. 18 at 126, 156 – 189.) For instance, for the brand-name drug Invega, beneficiaries who asked whether Invega would cost more than the generic version "in any phase of the Medicare Part D benefit" were told "no" which was false. (ECF No. 18 at 144.) Beneficiaries were also misled by statements indicating that they would have to pay for a larger percentage of the generic version of the branded drug when they exceeded certain coverage limits under Medicare Part D. (*Id.*) By referencing a larger percentage without the prices of the drugs, the statement was misleading because it suggests that the generic drug would cost more than the brand-name version when generics almost always cost the beneficiary and Medicare less. (*Id.*) For example, Relator notes that in 2019, Invega cost $1,240.45 whereas the generic version cost $265.25. (ECF No. 18 at 146.) Yet customer care representatives were told to tell beneficiaries when they asked whether Invega costs more than the generic version to say "no" and that if they got a formulary exception, in certain cases, they would owe 37 percent of the cost of the generic drug, versus owing 25 percent for Invega without mentioning the price disparity between the two drugs. (ECF No. 18 at 144-146.) Even after owing a smaller percentage of the cost of Invega, the generic version would still cost less than the brand-name version and thus, according to Relator, this is misleading. Defendants engaged in this alleged false and misleading behavior despite a 2012 Settlement Agreement with the FTC where they agreed not to make deceptive claims regarding "the price or cost of Medicare Part D prescription drugs." (ECF No. 18 at 12-13, 189.)

Relator states that Defendants embarked on a scheme to coverup the fraud, by improperly reporting what is known as "Prescription Drug Events" or "PDE" through the systematic and

knowing use of inaccurate "dispense as written" ("DAW") codes. (ECF No. 38 at 41.) How much Sponsors receive from the Government, through the Centers for Medicare & Medicaid Services ("CMS"), for Medicare Part D prescription benefits is impacted by the Sponsor's submission of PDEs. (ECF No. 18 at 28.) CMS gives monthly advances to Sponsors of the average cost of Medicare Part D prescription drug benefits, determined by a complex calculation and bidding process. (ECF No. 18 at 27.) If a Sponsor's actual costs, however, exceed the monthly advances, then the Sponsor may be able to recoup their costs through a risk-sharing agreement with CMS; likewise, if CMS's advances exceed the Sponsor's actual costs, the Sponsor may have to pay back and take a reduction in the funds it receives from CMS. (ECF No. 18 at 27.) PDEs are used to make this determination because they record each prescription for which the Sponsor has paid and they allow the Government to ensure compliance with Medicare Part D. (ECF No. 18 at 52-53.) The truthful and accurate submission of PDE information is a condition of payment from CMS. (*Id.*) Submitting a PDE requires filling out a form with several data fields one of which is titled "DAW/Product Selection Code" which requires selecting between ten numbers (0-9), called "DAW" codes, to indicate whether a generic drug was substituted for a brand-name one, and if not, why no substitution was made. (ECF No. 18 at 54.) Relator claims that Defendants knowingly used incorrect "DAW" codes to hide the fact that they were submitting PDE events to support payment from the Government on prescriptions that were not "valid" or were untruthful, inaccurate, and incomplete in violation of the relevant regulations. (ECF No. 18 at 226.) First, since the relevant federal regulations define a "valid prescription" as a prescription that complies with the requirements of state law and seventeen (17) states have laws that require that generic drugs must be substituted for a brand-name prescription, Relator claims many of the brand-name prescriptions upon which PDE events were submitted were not valid due to non-compliance with

state mandatory substitution laws. (ECF No. 38 at 23.) Second, Relator alleges Defendants knowingly submitted inaccurate DAW codes which falsely indicated that no generic existed (Code 0) and that wrongly stated that substitution was "permissible" when substitution was required by the relevant state law (Code 9). (ECF No. 38 at 42.) In other instances, even where state law did not require mandatory substitution, Defendants used codes that wrongly indicated that the physician or patient requested the brand-name drug when, in reality, it was the SilverScript plan that refused to dispense the generic drugs. (*Id.*) Relator provides several examples in which incorrect DAW codes were utilized.

The Relator contends Defendants' scheme was designed not just to thwart individuals from obtaining cheaper generic drugs, but also to financially benefit Defendants at the expense of the Government, Medicare beneficiaries, and taxpayers. Like many commercial insurance plans, many Medicare Part D beneficiaries must meet a deductible before a Sponsor's plan will cover their prescription drugs. (ECF No. 18 at 29.) When this deductible is met, Medicare Part D beneficiaries receive prescription drug coverage up to a certain annual amount. (ECF No. 38 at 16.) After hitting this annual threshold in prescription drug benefits, the Medicare Part D beneficiaries enter the so-called "Coverage Gap," sometimes also referred to as the "Donut Hole" of their plans. (ECF No. 18 at 30.) When in the "Coverage Gap," beneficiaries then typically pay out-of-pocket expenses, until they reach the threshold amount for "Catastrophic Coverage" to kick in. "Catastrophic Coverage" allows the Medicare Part D beneficiaries to receive prescription drug benefits again though under a reinsurance scheme, in which the United States Treasury pays 80% of the cost, the Sponsor pays 15%, and the beneficiary pays 5%. (ECF No. 18 at 30.)

According to Relator, Defendants' scheme costs the Government because many Medicare Part D beneficiaries were, due to the high cost of the brand-name drugs, pushed into the "Coverage

Gap" and "Catastrophic Coverage" phases sooner, leading to higher costs for the Government and beneficiaries. (ECF No. 18 at 82, 133.) This is because when calculating whether a beneficiary has met the Coverage Gap or Catastrophic Coverage threshold under Medicare Part D, a drug manufacturer's rebates for receiving a formulary preference for its brand-name drug are not deducted from the drug prices used to make this determination. (ECF No. 18 at 133.) In addition, certain authorized generics are eligible for a discount when beneficiaries fall into the Coverage Gap, whereas a brand-name drug may end up costing more. (ECF No. 18 at 143.) Thus, the Relator alleges, by preventing SilverScript plan enrollees from accessing cheaper drugs, thereby pushing them into Catastrophic Coverage sooner, Defendants were able to shift a larger financial burden of payment from themselves to the Government, who must then foot 80% of the bill. SilverScript also has "the largest number of beneficiaries of any Medicare PDP in the country who are eligible for the low-income subsidy whereby the Government subsidizes most of the Part D premium, deductibles and cost sharing." (ECF No. 18 at 18-20.) According to the Second Amended Complaint, the Government subsidizes 65% of the Medicare Part D drug costs of beneficiaries eligible for a low-income subsidy, which is a little over three times the amount it pays for individuals not eligible for subsidy. (ECF No. 18 at 97.) Thus, for SilverScript enrollees receiving the low-income subsidy, the implication is that the Government paid even more due to Defendants' scheme. Individuals receiving the low-income subsidy were less likely to complain, since the Government was subsidizing the increased cost from Defendants' scheme and did not see large differences in their out-of-pocket costs. (ECF No. 18 at 96, 97, 129.) Alexandra Miller, while employed by CVS Health, states that she reported Defendants' scheme to a supervisor, but was informed that senior management on the Executive Committee along with Chief of Compliance,

Patrick Jeswald, determined that the upside was much greater than the risk that it would be detected by the Government. (ECF No. 18 at 18.)

II. STANDARD OF REVIEW

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, (2007)). The plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." *Id.* To determine the sufficiency of a complaint under *Twombly* and *Iqbal*, a court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth"; and (3) "where there are well-pleaded factual allegations,…assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) (internal quotation marks omitted).

It is well-established, however, that *qui tam* actions brought under the FCA must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b). *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004) (citing U*.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)); *U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 143 (E.D. Pa. 2012). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Rule 9(b) requires, at a minimum, that "plaintiffs support their allegations…with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who,

what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal quotation marks omitted). However, courts will accept allegations on information and belief when "the facts at issue are peculiarly within the defendant's possession." *See Lincoln Benefit Life Co. v. AEI Life, LLC*, 800 F.3d 99, 107 n.31 (3d Cir. 2015); *Rockefeller*, 311 F.3d at 216. To satisfy the "particularity" requirement of Rule 9(b) at the pleadings stage, an FCA claimant may identify "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt.*, LLC, 754 F.3d 153, 155-56 (3d Cir. 2014). An FCA claimant is not required to show "'the exact content of the false claims in question' to survive a motion to dismiss" as requiring this sort of detail at the pleading stage would be "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Foglia*, 754 F.3d at 156, quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009).

III. DISCUSSION

Relator alleges a scheme by which Defendants, all market-dominating affiliated companies, colluded together to co-opt drug manufacturers' strategic anti-competitive agreements and reap the resulting benefits instead of passing them on to Medicare Part D recipients and the Government. According to Relator, Defendants were able to accomplish their scheme by gaming the nuances of the Medicare Part D system and drug benefit landscape. Yet in doing so, Relator alleges that Defendants violated the False Claims Act ("FCA"), 31 U.S.C §§ 3729, *et. seq*. Defendants frame the legal issues in this case as amounting to nothing more than Defendants simply complying with the law – or at minimum having an objectively reasonable interpretation

of the law. To Defendants, "there is nothing false about placing only a brand drug, and not a generic equivalent, on a formulary, nor can relator allege that defendant knowingly violated this non-existent rule…." (ECF No. 35-1 at 23.) But Defendants' incorrect characterization of Relator's allegations misses the mark in their attempt to reframe the legal issues before this Court. Just because the Government may permit a Medicare Part D plan to prefer brand-name drugs over generics on a formulary, does not mean that Defendants have a green light to enter into collusive agreements that cause Defendants to violate the requirements for receiving federal funds and then use those schemes to profiteer from Government healthcare spending. At this stage, where this Court must accept the well-pleaded allegations in Relator's SAC as true, the Court finds that Relator has sufficiently stated the elements of Counts I, II, and III of its FCA claims, but not as to Count IV.

The FCA allows whistleblowers, known as "relators," with inside knowledge of fraud against the Government to bring private actions in which the Government can choose to intervene and take over the prosecution of the case, or allow the relator to proceed on behalf of the Government. 31 U.S.C §§ 3730 (b)(1), 3730 (b)(2), 3730(c)(1)–(3). The FCA makes liable any "person"[3] who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). A similar subsection, known as the "reverse false claim" provision, prohibits the use of material records or statements (or concealment thereof) that "avoids or decreases an obligation to pay or transmit money…to the Government." 31 U.S.C. § 3729(a)(1)(G). The FCA also makes it unlawful to

[3] The FCA's use of "person" includes corporations and other business entities. *See Cook County, Ill. V. U.S. ex rel. Chandler*, 538 U.S. 119, 125 (2003).

conspire to commit a violation of the provisions of the FCA. 31 U.S.C. § 3729(a)(1)(C). Relator brings a claim under each of these subsections of the FCA.

Generally, to state a claim under the FCA, a relator must allege facts sufficient to satisfy four elements: (1) a false statement or fraudulent course of conduct; (2) made knowingly (scienter); (3) that was material, (4) causing the Government to pay out money or forfeit moneys due. *Universal Health Servs.. v. United States ex rel. Escobar*, 576 U.S. 176 (2016) (materiality); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011) (falsity, causation, knowledge). Even so, if there is a qualifying "public disclosure" and the relator is not an "original source" such claims must be dismissed under 31 U.S.C. § 3730(e)(4).

a. Original Source and Public Disclosure Bar

Defendants claim that Relator's action must be dismissed, without regard to the substantive merits of the claims, because the fraud Relator alleges was publicly disclosed before it filed this action. (ECF No. 35-1 at 56.) To preclude a relator from recovering FCA awards when the Government is already hot on the trail of fraud, Congress inserted what is known as the "public disclosure bar" to the *qui tam* provisions. *See* False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 3, 100 Stat. 3153, 3157 (1986) (current version at 31 U.S.C. § 3730(e)(4)(A)-(B) (2012)). This bar prevents a relator from pursuing a case and obtaining an award when the fraud allegations have already been subject to a qualifying public disclosure prior to the filing of the *qui tam* complaint. In particular, the public disclosure bar requires the court to:

> dismiss an action or claim under this section…if substantially the same allegation or transactions as alleged in the action or claim were publicly disclosed—(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4). The public disclosure bar, however, contains an exception for relators who are the "original source of the information" so that even if a public disclosure has occurred, a relator may still proceed if they qualify for this exception. 31 U.S.C. § 3730(e)(4)(A). Both the public disclosure bar and original source exception were amended by Congress in 2010, and these amendments are applicable to this case since the allegations occurred after 2010. *United States ex rel. Moore & Co., P.A v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016). An original source "means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit Court of Appeals has stated that to "'materially add[ ]' to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *See United States ex rel. Moore & Co. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 306 (3d Cir. 2016) (rejecting the defendant's argument that merely providing additional details of the fraud does not "materially add" because it only supports the publicly disclosed transactions). The original source exception is met, therefore, when a relator "contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Id.* at 307

Defendants argue that because "the schemes the relator alleges were publicly disclosed in congressional hearings, the news media, and federal reports, and the relator is neither the Attorney General nor an original source, this action must be dismissed." (ECF No. 35-1 at 56.) First, Defendants claim that SilverScript's formulary appeared in the "CMS Medicare Plan Finder Tool" – a Government interactive website that Medicare beneficiaries can view to determine costs – which they argue is a "Federal Report" for purposes of the public disclosure bar. (*Id.* at 57.) Defendants fail to cite any legal authority to support its claim this interactive tool is a "Federal Report" but regardless, it is not the mere placement of brand-name drugs on SilverScript's formulary that forms the basis of Relator's claims. Rather, Relator alleges a collusive scheme in which decisions to place certain drugs on a formulary were the product not of arms-length negotiations, as the Medicare Part D system envisioned, but rather secretive anti-competitive agreements that gamed the system and violated conditions required to receive federal funds. Defendants then cite to a series of articles that suffer from the same defect as none come close to describing the allegations in the SAC, but rather general information about brand-name drugs being covered drugs rather than generics. (ECF No. 35-1 at 58.)

Defendants also cite to two *qui tam* cases involving state mandatory generic-substitution laws for the proposition that using incorrect DAW codes constituted a public disclosure. Defendants, however, were not parties to these actions which involved different entities. *See United States v. Omnicare, Inc.*, 38 F. Supp. 3d 398 (S.D.N.Y 2014); *United States ex rel. Fox Rx, Inc. v. Walgreen Co.*, No. 12-cv-7382, 2014 WL 4066223 (S.D.N.Y. Aug. 18, 2014). Lastly, Defendants argue that a hearing before the Senate Finance Committee discussing the general use of rebates to incentivize placement of brand-name drugs over generics on a formulary where a CVS representative appeared and was questioned about its firewalls constitutes a public disclosure.

(ECF No. 35-1 at 59.) Yet nothing about the cited portions of this hearing indicates that the Government was aware of the underlying and specific fraudulent allegations in this case – it only suggests that the Government had some general suspicion that rebates were being utilized by drug manufacturers to incentivize placement of a branded drug on a formulary which was already public knowledge and, in some instances, can actually reduce costs, according to Defendants.

In sum, Defendants have failed to show that "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" and therefore, the public disclosure bar is not applicable. 31 U.S.C. § 3730(e)(4)(A); *see also United States ex rel. Moore & Co. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 303 (3d Cir. 2016) (defendant bears burden of showing that public disclosure bar applies). Notwithstanding, even if there was a public disclosure, Relator has sufficiently alleged that it is the original source by having knowledge that is "independent of" and "materially adds" to the alleged publicly disclosed information for similar reasons. *See also Moore*, 812 F.3d at 304-08 (a law firm, even though not an "individual" may be an "original source"). First, Relator has alleged that it had knowledge of the alleged fraud independent of the purported public disclosures, which one of the Relator's partners, Alexandra Miller, a former employee of CVS Health, acquired firsthand. (ECF No. 38 at 73.) Relator's SAC also "materially adds" to the alleged public disclosure through a detailed account of Defendants' alleged scheme, including specific cases and agreements to issue blanket formulary denials, the agreement and submission of incorrect DAW codes to hide the alleged noncompliance with Medicare Part D, and agreements not to stock generics at CVS Pharmacies, which violated firewalls between the CVS-related entities.

Therefore, the Court finds that it would be premature to dismiss this case on Defendant's Motion because the public disclosure bar is not warranted. Because the Relator has not pled itself

out of the case at the motion to dismiss stage, the Court recognizes that the public disclosure bar and original source exception may involve consideration of matters of fact and, thus, Defendants may reargue these issues at the more appropriate summary judgment phase, should they choose. *See, e.g., United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 718 F. App'x 101, 104 (3d Cir. 2018) (public disclosure and original source issues are "matters of fact" such that a motion to dismiss should be granted only if nonmoving party "plead[s] itself out of the case"); *see Franchitti v. Cognizant Tech. Sols. Corp.*, 555 F. Supp. 3d 63, 72-73 (D.N.J. 2021).

b. Falsity

Relator summarizes six ways in which the falsity requirement is satisfied including: (1) violating state generic-substitution laws (2) the submission of PDE data to CMS with false DAW codes; (3) the systematic and improper denial of formulary exception requests; (4) marketing material and predetermined, customer care representative call flows designed to mislead; (5) breaching promises made to the FTC to observe firewalls between CVS-related entities as required by agreements; and (6) falsely certifying compliance with federal law. Defendants argue that none of these allegations amount to false claims but rather involve what it characterizes as the mere "minutia of regulatory technical compliance." (ECF No. 35-1 at 9.) This Court need not determine all the enumerated ways in which the falsity element is satisfied, since many overlap, but will consider if Relator's allegations meet the requirements of Rules 12(b)(6) and 9(b) for each of Relator's FCA claims. At this stage of the proceedings, the Court confines its analysis to the most apparent false claims amongst those alleged.

There are three theories of liability under the FCA: (1) traditional FCA liability, (2) express certification theory, and (3) implied false certification theory. Traditional FCA liability, referred to as "factually false" claims, generally involves payment for goods and services that were never

provided or provided in a different form. *See, e.g. United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc*., 543 F.3d 1211, 1217 (10th Cir. 2008). Generally, this entails the submission of invoices to the Government that contain on their face false descriptions of the goods or services. Under the express certification theory, liability is triggered when a claim for payment submitted to the Government contains a false affirmative declaration of compliance with a contract provision, statute, or regulation material to the Government's decision to pay. *See United States ex rel. Wilkins v. United Health Grp., Inc*., 659 F.3d 295, 305 (3d Cir. 2011), *abrogated on other grounds by Escobar*, 579 U.S. 176 (2016). Under implied false certification theory, when a defendant submits a claim to the Government, it "impliedly certifies" that it has complied with all the important and "material statutory, regulatory, or contractual requirement[s]." *Escobar*, 579 U.S. at 177. If the claim does not "disclose the defendant's violation of a material statutory, regulatory, or contractual requirement," the claim constitutes a false claim under the FCA. *Id.* Thus, an implied false certification differs from express certification because for implied false certifications, defendants may be liable for submitting claims that do not explicitly state they are complying with the law.

An implied false certification is sufficiently supported by allegations showing two conditions: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190. In *Escobar*, a patient and beneficiary of Medicaid, died after being treated by a mental health care facility where the providers were not licensed in the manner required by Medicaid regulations. *Id.* The relators claimed that the providers had violated the FCA by submitting claims for services provided by

purportedly qualified professionals, when in fact, the professionals lacked the required qualifications. The relators claimed the false claims occurred when Defendants submitted claims "for payment using payment codes that corresponded to specific counseling services, [the provider] represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment." *Id.* at 189. The provider also "made further representations in submitting Medicaid reimbursement claims by using [codes to identify] specific job titles," which falsely implied that the services were provided by staff with particular licenses. *Id.* The Supreme Court granted *certiorari* to resolve the circuit split as to "the validity and scope of the implied false certification theory of liability." *Id.* at 186. In analyzing the validity of the theory, the Court found that the term "false or fraudulent claim" in the FCA encompasses more than just claims with express falsehoods because it incorporates the common law meaning of "fraud." *Id.* at 185-86. The Court also explained that "half-truths" omitting critical information can be actionable misrepresentations. *Id.* at 188. The Court noted that "[r]espondents may well have adequately pleaded a violation of § 3729(a)(1)(A)" but vacated the judgment and remanded for proceedings consistent with the opinion. *Id.* at 190.

Relator argues that Defendants' noncompliance with what they refer to as "state mandatory generic-substitution laws" and submission of PDE data to CMS with incorrect DAW codes to conceal their noncompliance, constitutes false claims under an implied and express false certification theory. The Court views the allegations as ones pointing to implied false certifications. Under the relevant federal regulations, a sponsor, such as SilverScript, may only provide prescription drug benefits for those drugs that are dispensed upon a "valid" prescription, which is defined as those that "compl[y] with all applicable State law requirements constituting a valid prescription." 42 C.F.R. §§ 423.100, 423.104, 423.101; Changes to the Medicare Advantage and

the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22072, 22139 (Apr. 12, 2012) ("Since the inception of the Part D Program, [CMS] ha[s] consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law").[4] In other words, state law applies in determining what constitutes a valid prescription and whether Part D benefits are available for these drugs; a Sponsor may not receive payments from CMS for invalid prescriptions.

The parties dispute how many jurisdictions and which states have mandatory generic substitution laws. According to Relator, seventeen jurisdictions require that generic drugs must be substituted for brand-name drugs when the generic drug is cheaper for the beneficiary, and that these requirements apply regardless of whether the generic drug is on the Sponsor's formulary. (ECF No. 38 at 22.) Although Defendants concede that thirteen jurisdictions do direct pharmacists to substitute less expensive therapeutically equivalent drugs in certain instances, it seems to interpret those laws in a different way than Relator. (ECF No. 35-1 at 31.) Defendants appear to argue that these mandatory generic substitution laws can only logically mean that "less expensive" drugs are those that are less expensive *and* on the SilverScript plan formulary, meaning from the same formulary and drugs subject to Defendants' alleged collusive scheme. (ECF No. 35-1 at 31-33.) The only rationale Defendants give for this interpretation is that it makes "little sense" to suggest that state legislators intended to require generic substitution under state law when a generic drug was not on a Medicare Part D plan formulary. (*Id.*) Otherwise, according to Defendants, the generic drugs will not count towards a beneficiary's out-of-pocket expenses in Medicare Part D's

[4] Defendants claim that this regulation does not require compliance with state generic-substitution laws, yet fails to cite anything in support. (ECF No. 42 at 15.)

phased cost-sharing system, though Defendants do little to explain how this might be more costly and how this is not a factual issue.[5] (*Id.*)

Defendants, again, fail to cite to legal authority for the proposition that the mandatory generic substitution laws do not apply when a drug does not appear on a Medicare Part D plan formulary. One could also argue that a statutory interpretation that allows private entities to usurp state law and prevent generic substitution as required simply by devising a list that only covers brand-name drugs makes "little sense" particularly when CMS deems dispensing "valid" prescriptions in compliance with state law paramount.[6] The Court notes that at least nine states use the word "shall" in reference to selecting a less expensive therapeutic equivalent indicating that drug substitution for less expensive drugs is generally required in these states, with some nuances and carveouts depending on the jurisdiction. *See* Fla. Rev. Stat. § 465.025(2); Ky. Rev. Stat. § 217.822(1); N.J. Stat. § 24:6E-7; N.Y. Educ. Law § 6816-a(1); 35 Pa. Stat. § 960.3; Wis. Stat. § 450.13; Mass. Gen. Laws ch. 112 § 12D; R.I. Gen. Laws § 5-19.1-19; W. Va. Code § 30-5-12b(f), (g). These nine state laws do not contain a carveout for drugs not appearing on a Medicare Part D Sponsor's formulary, nor has this Court seen any authority or guidance suggesting this.[7] Therefore, this Court finds that in at least these states, there is a mandatory drug substitution

[5] Presumably, Defendants are arguing that when not on a formulary, out-of-pocket expenses are not counted for purposes of the Coverage Gap as they are not "covered." In the SAC, Relator indicates that generic drugs that are granted formulary exceptions are covered and that Defendants issued blanket denials. In addition, many of the state laws provide that a generic need not be substituted if a prescriber expressly provides for no substitution or the purchaser requests otherwise. *See, e.g.* Fla. Rev. Stat. § 465.025 (pharmacists are required to substitute a "less expensive, generically equivalent drug product" for a brand name, unless the prescriber expressly indicates the brand-named drug is medically necessary or the purchaser requests otherwise). Beneficiaries facing increased out-of-pocket expenses could request the brand-drug or get their physicians to request them.

[6] Conflicting with Defendants' argument, some of these states have their own "formularies" set at the local level from which a generic substitute must be found. *See, e.g.* Fla. Rev. Stat. § 465.025(2) (formulary created by community pharmacy); Ky. Rev. Stat. § 217.822(1) (formulary created by the "board"); N.J. Stat. § 24:6E-7 (list of interchangeable products created by the "council")

[7] In at least one state, the statute actually notes that for Massachusetts Medicaid beneficiaries (MassHealth), the pharmacists shall notify the prescriber "if a substitution to a narrow therapeutic index immunosuppressant drug for the treatment of an organ or tissue transplant is made" indicating that the state legislators enacted this statute with

law for less expensive therapeutic equivalents that generally applies unless the state law has an exception, none of which exclude generic drugs not on a Medicare Part D formulary.

Defendants also argue that these mandatory generic substitution laws only apply to pharmacists, not sponsors or PBMs, and therefore, such claims are not false within the meaning of the FCA. (ECF No. 35-1 at 30.) However, Defendants miss a critical point: a Sponsor needs to attest to and remains responsible for the accuracy, completeness, and truthfulness of all claims data submitted to CMS, such as PDEs with DAW codes, including for related entities. Indeed, the regulations provide that "[n]otwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS." 42 C.F.R § 423.505(i). The regulations also specify that "as a condition for receiving a monthly payment" from CMS, the Sponsor, through the proper company representative, must certify the "accuracy, completeness, and truthfulness of all data related to payment." *See* 42 C.F.R. §§ 423.505(k). In addition, 42 C.F.R. § 423.505(k)(3), which relates to the certification of claims data by plan sponsors and their contractors, entitled "Certification of data that determine payment," provides, in relevant part, that the:

> CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3)…are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

Medicaid in mind. Mass. Gen. Laws ch. 112 § 12D. Another state statute specifically refers to "lowest retail cost-effective brand" meaning that the statute refers to retail price as the benchmark. W. Va. Code § 30-5-12b(f), (g)

Id. at § 423.505(k)(3). Sponsors also need to comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse…." 42 C.F.R. § 423.505(h)(1). Thus, SilverScript was required to certify that the claims data, including PDEs, were accurate, complete, and truthful. Because federal law requires compliance with state law as to the validity of a prescription, Defendants were also required to comply with state mandatory generic substitution laws.

According to Relator, SilverScript made false certifications warranting the accuracy, completeness, and truthfulness of the claims data they submitted to CMS and compliance with federal and state law, despite their noncompliance which they concealed through incorrect DAW codes for "invalid" prescriptions. The SAC provides examples of the utilization of incorrect DAW codes for brand-name drugs that were dispensed when other cheaper therapeutically equivalent drugs were available. (ECF No. 38 at 41-42; ECF No. 18 at 117, 122, 139, 141, 172, 194.) The SAC alleges that CVS Health routinely utilized untruthful, inaccurate, and incomplete DAW Codes, such as DAW Code 0, DAW Code 1, DAW Code 2, DAW Code 5, or DAW Code 9, because it chose not to substitute a generic for a brand-name drug as required by Medicare Part D that incorporated state mandatory generic substitution laws. Thus, the CVS Health entities' certification in its PDE information was not "accurate, complete and truthful" but intentionally false.

Relator alleges that the incorrect coding was not an innocent mistake, but purposeful to conceal noncompliance with the law. (ECF No. 38 at 44.) Many of these specific examples along with the overall allegations related to executive approval support this allegation. Indeed, Alexandra Miller, while employed by CVS Health, and who served in an executive position, states that she reported Defendants' scheme but was informed that senior management on the Executive Committee along with Chief of Compliance, Patrick Jeswald, determined that the upside was much

greater than the risk that it would be detected by the Government. (ECF No. 18 at 18.) These allegations sufficiently set forth the who, what, where, and how for purposes of Rule 9(b). They are also suggestive of a scheme to thwart beneficiaries from obtaining cheaper drugs altogether, regardless of the clinical impact it might have on them.

The case *Sturgeon v. PharMerica Corp.*, 438 F. Supp. 3d 246 (E.D. Pa. 2020) provides guidance. In *Sturgeon*, the relators alleged, among other claims, that the defendant, a pharmacy that fills prescriptions for nursing homes and long-term care facilities, violated the applicable federal and state law by substituting more profitable brand-name drugs for generic drugs. *Id.* at 275. Each time the defendant submitted a claim for reimbursement for dispensation of the substituted brand-name drug for the generic drug, the relators claimed that the defendant falsely certified compliance with all applicable law and regulations. *Id.* Similar to this case, the relators argued that this kind of alteration was unlawful because to be eligible for Government reimbursement, federal and state regulations require that pharmacies dispense generic drugs that are therapeutically equivalent to brand-name drugs when the generic is cheaper. *Id.* Substitution also required physician consent in many jurisdictions. *Id.* at 276. In either case, the defendant could not legally seek reimbursement from Medicare or Medicaid. The *Sturgeon* court agreed, denying the defendant's motion to dismiss as to relators' FCA claim on this ground. *Id.* Though this case is the inverse scenario of the present matter – which involves the failure to substitute a brand-name drug for a generic drug in violation of state law rather than a substitution of a brand-name drug for a generic drug as in *Sturgeon* – its reasoning is on point. First, it accepted the notion that violation of a state law regarding brand-name and generic drug substitutions could constitute a false claim. Second, in *Sturgeon*, the defendant had argued, similar to Defendants here, that the cost of a drug depended on the defendant's own formulary development process. Nonetheless, the

Sturgeon court noted that "[it] may well turn out that under the relevant formulary, the brand-name drugs dispensed were no more expensive than the generics" but since the relators had alleged that the generics were, in fact, cheaper, such argument was more appropriate on a motion for summary judgment. *Id.* at 276 n.203.

The same can be said here where many of the arguments Defendants make relate to those more properly brought on a motion for summary judgment. At this stage of the proceedings, the Court must accept Relator's well-pleaded allegations as true. Thus, the Court finds that the SAC adequately alleges that Defendants, by failing to comply with state mandatory generic substitution laws – a pre-requisite for a "valid prescription" under Medicare Part D – and then "mak[ing] specific representations about the goods…provided," *i.e.* the submission of PDEs with false DAW codes despite certifications under 42 C.F.R. § 423.505(k)(3), Defendants made "misrepresentations [that were] misleading half-truths" amounting to an implied false certification. *Escobar*, 579 U.S. at 190.

c. Scienter

Defendants argue that Relator has failed to allege sufficient facts to show that the scienter requirement of the FCA is satisfied because they had an "objectively reasonable interpretation of the Medicare Act and CMS regulations that a plan sponsor can make a formulary decision that includes a brand drug but not its generic equivalent" which can be administered by its PBM with covered drugs dispensed by its network pharmacies. (ECF No. 35-1 at 28.) They also claim that they had an "objectively reasonable" interpretation of generic substitution laws citing a Fair Credit Reporting Act case, *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007), and an unpublished Third

Circuit opinion, *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2016). (ECF No. 42 at 16).[8]

To show scienter, a relator need not show specific intent to defraud, but must demonstrate that the defendants: (1) possessed "actual knowledge of the information" ; (2) acted "in deliberate ignorance of the truth or falsity of the information," or ; (3) acted "in reckless disregard of the truth or falsity of the information." 31 U.S.C. §§ 3729(b)(1)(A)-(B). Though specific intent to defraud is not required, allegations of knowledge are still subject to the plausibility standard set forth in *Twombly* and *Iqbal*. *See U.S. ex rel. Pilecki-Simko v. Chubb Instit.*, 443 F. App'x 754, 760 n.17 (3d Cir. 2011).

In *Safeco,* the Supreme Court held that a defendant lacks scienter to violate the Fair Credit Reporting Act if his interpretation of the law was not "objectively unreasonable." 551 U.S. at 69. Since *Safeco*, several Circuit Court of Appeals have applied the "objectively unreasonable" standard to FCA cases. *See, e.g. United States ex rel. Olhausen v. Arriva Med. LL*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022) (per curiam); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 2022 WL 4396367, at *1 (4th Cir. Sept. 23, 2022) (en banc) (affirming 499 F. Supp. 3d 184, 207 (D. Md. 2020), without opinion); *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 459 (7th Cir. 2021), *rehearing den.* (Dec. 3, 2021), *pet. for cert. docketed*, No. 21-1326 (U.S. Apr. 5, 2022); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552

[8] The United States Supreme Court recently granted certiorari in *United States ex rel. Schutte v. Supervalu Inc*., 2023 WL 178398 (Jan. 13, 2023) and *United States ex rel. Proctor v. Safeway, Inc*., 2023 WL 178393 (Jan. 13, 2023), two Seventh Circuit cases that address whether the Supreme Court's decision in *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007) applies to FCA cases. Even if the Supreme Court ultimately concludes that it does, any such interpretation would have to be consistent with the FCA's "deliberate ignorance" knowledge standard so as not to effectively neuter the FCA by allowing fraudsters to escape liability by coming up with after-the-fact justifications.

(9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of K.C.*, 833 F.3d 874, 879-880 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290-291 (D.C. Cir. 2015). In *Streck v. Allergan, Inc*., the Third Circuit adopted the "objectively unreasonable" standard in an FCA case, though in a non-precedential opinion. 746 F. App'x at 106 (affirming motion to dismiss because defendants held a reasonable-but-wrong interpretation of their drugs "Average Manufacturer Price").

The parties dispute whether this standard applies here. The Court, however, need not decide whether this standard applies, because even if it does, Defendants have pointed to no authority to support their interpretation. Indeed, the only thing Defendants point to is their own supposition that they have interpreted the law correctly. That is not enough to satisfy the standard. *See Streck*, 746 F. App'x at 106 ("[b]asing a defense on a reasonable, but erroneous, interpretation of a statute includes three distinct inquiries: (1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance").

Safeco is not the blank check Defendants appear to think it is. It does not give an all-purpose liability escape hatch. The plain text of the relevant state statutes and federal regulations do not support Defendants' interpretation, nor are they ambiguous – they simply require that drug substitutions occur when certain conditions are met along with specific exceptions. Not liking the trickle-down implications of a statute does not make it ambiguous. And it is not for this Court to second guess the plain meaning of state statutes or the federal regulations that incorporate state law, if there is nothing that says a contrary interpretation is warranted. Here, Relator has pled sufficient facts to demonstrate a basis for inferring that Defendants acted with actual knowledge,

deliberate ignorance, or reckless disregard for the truth or falsity of the reporting to CMS. The SAC alleges that SilverScript and its PBM certified its compliance with federal and state law, in collusion with CVS Pharmacy, all while controlled by the same entity, CVS Health, that knowingly, or at minimum, with deliberate ignorance, directed the violation of these laws. Relator claims that Defendants' conduct was not the product of innocent mistakes, but purposefully as part of a larger fraudulent scheme and has provided exemplar cases along with specific allegations to back that up. In response, all Defendants argue is that their interpretation was "objectively reasonable" without any evidence that it is. Accordingly, the Court finds that the SAC sufficiently alleges scienter.

d. Materiality

Defendants claim that the "DAW codes were immaterial because the brand and only the brand was on-formulary and, thus, the only drug that could be legitimately reimbursed." (ECF No. 42 at 19.) Defendants also state that since the Government "has known about these allegations for years and taken no action is strong proof of immateriality" but as this Court has previously noted, nothing Defendants point to show that the Government was aware of the scheme Relator alleges. (ECF No. 42 at 10.) Lastly, Defendants argue that it is "not plausible" that CMS prefers Medicare Part D beneficiaries "bear the full cost of a generic equivalent" instead of a Sponsor's plan paying for the on-formulary drug. (ECF No. 42 at 15). In essence, Defendants are arguing that even if they colluded to create SilverScript's formulary and deny exceptions so that generic drugs are not covered, their own actions that now result in the cost of these drugs being passed onto consumers may now be used to conclude lack of materiality. This argument is unavailing as the requirements of the FCA cannot be read to allow Defendants to define their own liability.

Rather, a materiality inquiry under the FCA is a holistic, totality-of-the-circumstances examination of whether the false statement has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *see Escobar*, 579 U.S. at 193. The Government's "decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive" of materiality. *Escobar*, 579 U.S. at 194; *see also United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017). While materiality "cannot be found where noncompliance is minor or insubstantial," it may be found where the Government "consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."[9] *Id.* In this context, as in all others, materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 193 (alteration in original) (quoting 26 R. Lord, WILLISON ON CONTRACTS § 69:12, p. 549 (4th ed. 2003)).

The Government designed the Medicare Part D system to decrease costs through market competition. It did not envision a system where the Government's costs were purposefully increased by potential bad actors or merged companies who colluded and took steps at every level of the corporate Medicare reimbursement chain to profiteer at the Government's expense and prevent detection. It also did not envision a system where Medicare Part D beneficiaries, many of whom are receiving low-income subsidies, are prevented from getting critical and lifesaving prescription drugs because market-dominating affiliated companies, to extract more federal funds, conspired and denied access to less expensive, therapeutic equivalents.

[9] Defendants appear to suggest that *Escobar* requires proof that CMS would not reimburse claims had they known of the alleged false certifications of compliance with state mandatory generic substitution laws, but this is not the standard set forth in *Escobar*.

This is what Relator's allegations boil down to. The FCA is concerned with fraud on the Government, and that is precisely what Relator alleges occurred in this case. And though Defendants attempt to split hairs, the Court is unconvinced by Defendants' argument that its alleged conduct is not material to the Government's decision to pay. That the Government continues to pay for claims for a formulary that only designates brand-name drugs as covered by a Medicare Part D plan is not surprising, since by Defendants' own admission, rebate agreements can lead to decreased costs and make the brand-name cheaper than generic alternatives. But that is not what is alleged to have occurred here. Rather, when the Government thought it was paying for "valid" prescriptions, it paid for, according to Relator, invalid ones. And when it asked for specific DAW codes, so that it could verify what prescriptions it was paying for and why, and if they complied with Medicare Part D, it got, according to Relator, fabricated ones, even though accurate PDEs were a condition of payment. In at least one instance, it is alleged that Defendants' scheme prevented a beneficiary from obtaining a potential life-saving and critical prescription drug. All of this cost the Government more, not less. None of these facts could be discovered based on a formulary alone. The Court finds that Relator has sufficiently set forth allegations in the SAC to support that the Government would not have paid for these claims had it known of Defendants' alleged scheme. Therefore, this Court finds that Relator has sufficiently set forth sufficient allegations under Rule 9(b) and the plausibility standard to satisfy the materiality requirement.

e. Causation – CVS Health and CVS Pharmacy

CVS Health claims that it should be dismissed from this action because as the "parent company" it is "not submitting claims, making formulary choices, nor making any representations to CMS about formulary choices" but rather "merely an owner of the entities that are." (ECF No. 35-1 at 22.) CVS Pharmacy also argues that it should be dismissed from this action because it is

a pharmacy that "does not decide which drugs a Part D plan sponsor chooses to cover" and "does not make a plan's formulary choices nor makes any certification to the Government about the plan's formulary choices when dispensing a covered prescription." (*Id.*) In essence, as to CVS Health and CVS Pharmacy, Defendants are arguing that there is no causation because they did not cause the Government to pay out funds for Medicare Part D. Defendants do not otherwise argue that causation is lacking.

Though there must be "some level of direct involvement in causing the submission of false claims to the Government necessary for direct liability under the FCA," the FCA does impose liability on those who "cause" the submission of false claims. *Cf. United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 513 (E.D. Pa. 2016); 31 U.S.C. § 3729 *et seq.* In particular, subsection (a)(1)(A) of § 3729 imposes liability on "any person who…knowingly presents, *or causes to* be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). Subsections 3729(a)(1)(B) and (a)(1)(G) repeat that emphasis. 31 U.S.C. § 3729(a)(1)(B), (G); *see also* 31 U.S.C. § 3729(b)(2)(A) (broadly defining "claim" as including "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that…is presented to an officer, employee, or agent of the United States.") Thus, the FCA imposes liability on an entity that commits a violation through its control of another entity. *See, e.g., United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431 (E.D. Pa. 2020) (allegations that parent company directed and controlled the fraud were adequate to survive motion to dismiss). And if a person or entity knowingly participates in a scheme that, if successful, would ultimately result in the submission of a false claim to the Government, that person or entity has caused those claims to be submitted. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004) (finding

sub-contractor whose scheme was a substantial factor in the contractor's submission of a false claim could be found to have caused the submission.)

The SAC alleges that both CVS Health and CVS Pharmacy caused false claims to be submitted to the Government. For instance, the SAC alleges that CVS Health, through its Executive Committee and Board of Directors, specifically directed, over internal objections from Relator, that its subsidiaries implement Defendants' alleged fraudulent scheme because the upside was greater than the risk of detection. (ECF No. 18 at 18; ECF No. 38 at 74.) As to CVS Pharmacy, Relator claims that they knowingly operated under a policy that caused other CVS-related entities to present false claims to the Government. Relator claims that CVS Pharmacy affirmatively joined in the scheme by refusing to stock cheaper authorized generics of several brand-name drugs, including Epclusa, Harvoni, Advair Diskus, and Ventolin HFA. (ECF No. 38 at 76.) The SAC reports that CVS Pharmacy also systematically reported false DAW codes to misrepresent the reason as to why prescription brand-name drugs were being dispensed over cheaper generic equivalents, hiding from CMS state law noncompliance despite the accuracy of these codes and state law compliance being a condition of receiving Government money. (*Id.*) In order for the scheme to work, CVS Pharmacy had to follow CVS Health's directive to not comply with state mandatory generic substitution laws, so CVS Pharmacy, according to the SAC, was not an innocent and passive subsidiary, but rather had direct and substantial involvement in causing the submission of false claims. Therefore, there are sufficient allegations at the pleadings stage to support the conclusion that CVS Pharmacy and CVS Health caused the submission of false claims.

f. Conspiracy to Violate the FCA

Under the FCA, conspiracy to violate the Act is a violation of the Act itself. 31 U.S.C. § 3729 (a)(1)(C).[10] To state a claim for conspiracy, Relator must describe the general composition of the conspiracy, its broad objectives, and the general roles in the conspiracy. *See Rose v. Bartle*, 871 F.2d 331, 366-67 (3d Cir. 1989); *United States ex rel. Budike v. Peco Energy, No*. 07-4147, 2013 WL 5890650, at *5 (E.D. Pa. Nov. 4, 2013) (collecting cases). "In order to state a conspiracy claim under the [Federal False Claims Act], a plaintiff must allege (1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." *United States v. Medco Health Sys., Inc.*, No. CIV. 12-522 (NLH), 2014 U.S. Dist. LEXIS 135767, at * 11 (D.N.J. Sept. 26, 2014) "Critically, '[t]he essence of a conspiracy under the Act is an agreement between two or more persons to commit fraud.'" *Id.*

The SAC alleges how CVS Caremark worked with other Defendants to co-opt drug manufacturers' rebate agreements so that they could pad their bottom lines. The SAC also alleges that CVS Caremark required CVS Pharmacy to no longer stock certain generic drugs so that SilverScript enrollees could not obtain them. The SAC alleges that Defendants agreed to deceive Part D beneficiaries about the price and availability of generic drugs and facilitated the drug manufacturers' efforts to delay competition through evergreening, product hopping, pay-for-delay, sham patent litigation, sham Citizen's petitions, authorized generics, and other schemes. Relator claims Defendants accomplished this by various misleading marketing material and requiring customer care representatives to make false and misleading statements to beneficiaries. (ECF No.

[10] Defendants refer to the intra-corporate conspiracy doctrine which holds that a wholly-owned subsidiary cannot conspire with its parent company since one cannot conspire with itself. *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 777 (1984); (ECF No. 35-1 at 55.) The SAC refers to Defendants as "affiliated" or "subsidiary" with only a loose mention of "wholly-owned subsidiaries." This argument is premature without the benefit of discovery as to the corporate structure.

18 at 11.) Relator provides several SilverScript predetermined call flows and training instructions that appear to be designed to mislead, along with specific instances where beneficiaries were misled by customer care representatives. (ECF No. 18 at 156 – 189.) Alexandra Miller, who was employed by CVS Health for nineteen (19) years and even served in an executive role, alleges that she was informed senior management decided to proceed with their scheme despite her complaints because they felt the company was at little risk of detection by the Government. (ECF No. 18 at 18.) At the pleadings stage, the SAC provides sufficient circumstantial evidence from which the Court can easily infer the existence of an agreement to violate the FCA amongst all Defendants and steps taken in furtherance of that scheme. *See United States ex rel. Travis v. Gilead Sciences, Inc. Travis*, 596 F. Supp. 3d 522, 541 (E.D. Pa. 2022) (Court can "infer the existence of an agreement"…to violate the False Claims Act "by specifically directing donations to subsidize the copays of patients").

g. Reverse False Claims

Relator brings a claim under Section 3729(a)(1)(G) known as the reverse false claims section; it provides liability where one acts improperly, not to get money from the Government, but to avoid having to pay money to the Government. It also creates liability for knowingly retaining Government overpayments once it is known that there is an obligation to return them, without needing to establish that defendant submitted a false claim or used a false recording. *See United States ex rel. Customs Fraud Investigations v. Victaulic Co.*, 839 F.3d 242, 254 (3d Cir. 2016); *see also* 42 U.S.C. § 1320a-7k(d)(2) (2018).

Relator argues that Defendants – by knowingly violating firewall requirements with the FTC and refusing to pay the fines that might be due as a result of a violation of this agreement – violated their obligations to pay the Government. (ECF No. 38 at 41.) In support Relator cites a

district court opinion, *United States ex rel. Boise v. Cephalon, Inc.*, which held that the violation of a corporate integrity agreement created an "obligation," even though the agreement specified that "failure to comply…*may lead to* the imposition of" fines. No. 08-287, 2015 WL 4461793, at *1, *6-7 (E.D. Pa. July 21, 2015) (emphasis added). Defendants argue that because Relator does not provide a factual basis for a reverse false claim that is distinct from its other FCA claims, it should be dismissed as redundant. (ECF No. 35-1 at 22 n. 5; ECF No. 42 at 27); *see also United States ex rel. Alejandro v. Phila. Vision Ctr.*, 2022 WL 294548, at *9 (E.D. Pa. Feb. 1, 2022); *Purcell v. Gilead Scis., Inc*., 439 F. Supp. 3d 388, 400-401 (E.D. Pa. 2020). Defendants also argue that failure to voluntarily pay penalties which have not even been assessed cannot be used to support a reverse false claim. (ECF No. 42 at 27.)

The Court agrees with Defendants. For the reverse false claims provision to apply, there must be a clear obligation or liability to the Government, which cannot be premised on a future discretionary act. *United States ex rel. Petras v. Simparel, Inc*., 857 F.3d 497, 505 (3d Cir. 2017); *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 446 (3d Cir. 2004) (without a clear obligation to credit the Government, no FCA liability could be imposed). Regulatory fines and penalties are not considered "obligations" because they are contingent on the Government's prosecutorial discretion. *Sturgeon v. Pharmerica Corp*., 438 F. Supp. 3d 246, 279 (E.D. Pa. 2020). Unlike the case Relator cites, *Boise v. Cephalon, Inc.*, Defendants have not entered into a contractual agreement with stipulated penalties. Here, the alleged overpayment is much more conjectural. Therefore, the Court finds that Defendants' Motion to Dismiss is warranted as to Relator's reverse false claim.

IV. CONCLUSION

For the reasons discussed above, the Court will deny in part and grant in part Defendants' Motion to Dismiss.

An appropriate Order follows.

IT IS SO ORDERED.

BY THE COURT:

/s/ John Milton Younge
JUDGE JOHN MILTON YOUNGE